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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/748,133

12/27/2000

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EXAMINER

AZPURU, CARLOS A

ART UNIT

PAPER NUMBER

1615

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03/10/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/748,133	<b>Applicant(s)</b> MUMPER ET AL.	
	<b>Examiner</b> Carlos A. Azpuru	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-16 and 18-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-16 and 18-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10312008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt is acknowledged of the amendment filed 12/04/2008. An information disclosure statement was also filed on 10/31/2008.

The rejection of claims 1, 3-16, 18-34 under 35 USC 102(b) for Biegajski et al is maintained in this action. The full text of which is found on the previous action.

### ***Response to Arguments***

Applicant's arguments filed 12/04/2008 have been fully considered but they are not persuasive.

Applicant argues that claim 1 might be broadly construed to read on laminates and adhesives films. This is indeed the case, and while the preamble breathes life into a claim the claim as written can be interpreted as reading on these types of drug delivery systems. While the newly amended claim reads on a gel, the claimed structure need only comprise a gel, but is in no way limited to this. This is not being interpreted more broadly than applicant is claiming because applicant's definition in the specification is nothing more than the recognized definition of a gel. Certainly, applicant must agree that there is nothing special about the gels being claimed by applicant. While applicant seeks to limit the claimed invention to this gel, the claim language merely states that the invention "comprises" a gel and therefore only need by part of the claimed invention. Nothing in the definition or claim limit the claimed invention to gel in the exclusive.

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Nothing in the claim excludes backing layers or any other structural feature taught by Biegajski et al.

The claimed language uses "comprising" to set out the invention. While the word gel does indeed limit the invention, it does not do so to the exclusion of any other features by maintaining this open ended language. The only closed language used is in the definition of the gel as cited above, and as long as the claimed invention has this gel, it meets the limitations of the claims as now set out.

Applicant argues that the claims fail to set out "water-insoluble swellable mucoadhesive particles". Again however, this terminology is inherent to the definition of a gel and does not set out any limitation not familiar to the ordinary practitioner.

For these reasons, the rejection under 35 USC 102(b) over Biegajski et al is maintained.

The following are new rejections cited in view of applicant's newly filed information disclosure statement:

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to

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identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 3-16, 18-34 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-33 of copending Application No. US 2002/0132008 (Us'2008). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

US'2008 sets out a gel having a solvent vehicle, at least one pH-insoluble swellable mucoadhesive polymer, at least one pH-sensitive film forming polymer, and a molecule of interest (see claim 1). The amount and type of solvent is set out in claim 2. Types of water swellable mucoadhesive polymers are specifically recited in claims 3-5. pH-sensitive polymer are also identical in claims 6-8. Molecules of interest are set out in claims 9-14. The next claims (16-33) largely repeat the same invention. Applicant is claiming the same invention as set out in US'2008.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-16, 18-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/48477 (Theramex).

Theramex discloses a gel composition which comprises a solvent system as set out at page 4 lines 1—32. Gelling agents (mucoadhesive polymers) are found at page 5, lines 21-33. Film forming agents are found at page 7, lines 9-34; page 6 and line 1 of page 7. The gel is used to administer normegestrol (see page 8, lines 13-16). The gel is disclosed for topical administration (see claims). While the disclosure also includes mixtures chosen from these components and potentially adds absorption promoters, the ordinary practitioner would find it well within his or her skill to use such an admixture for the same art recognized purpose with a reasonable expectation of similar therapeutic results. The instant invention would have therefore been obvious to one of ordinary skill in the art at the time of invention given the claims of Theramex.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-9, 14-16, 18-24, 27, 30-34 rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/17251 (Virotex).

Virotex discloses a composition which contains a mucoadhesive polymer as well as a film forming polymer (See page 10, lines 5-27). Specific film forming polymers are found at page 11, lines 24-28; page 12, lines 1-10. Crosslinkers are found at page 12, lines 14-19 and include polyalkylene glycol. Bioactives are found at page 14, lines 9-28; page 15; page 16, lines 1-4. The compositions are evaluated in water (See Table 1, examples 1, 12 and 17). The instant claims are anticipated by Virotex.

### ***Conclusion***

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 10/31/2008 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos A. Azpuru/

Carlos A. Azpuru



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Primary Examiner, Art Unit 1615

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